In re Lundak

(CA FC)
227 USPQ 90

Decided September 16, 1985
No. 85-887
U.S. Court of Appeals Federal Circuit

Headnotes

PATENTS

1. Specifications -- Sufficiency of disclosure (§ 62.7)

35 USC 112 does not require transfer of invention sample to independent depository prior to filing date of patent application, and thus applicant's deposit of sample of cell line with American Type Culture Collection, which was made after filing but prior to issuance of patent, and which is referred to in specification, meets statutory requirements.

2. Specifications -- Sufficiency of disclosure (§ 62.7)

Specification which did not identify actual location of cell line sample at time of filing but which otherwise contained complete description of invention met requirements of constructive reduction to practice, and insertion of depository data after filing is not new matter under 35 USC 132.

Particular Patents -- Cell Line

Lundak, application Serial No. 247,656, High Fusion Frequency Fusible Lymphoblastoid Cell Line, rejection of Claims 1 and 2, reversed.

Case History and Disposition:

Appeal from United States Patent and Trademark Office, Board of Patent Appeals.

Application for patent of Robert L. Lundak, Serial No. 247,656. From decision upholding rejection of Claims 1 and 2, applicant appeals. Reversed.

Attorneys:
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Harris A. Pitlick, Associate Solicitor, U.S. Patent and Trademark Office (Joseph F. Nakamura, Solicitor, and John W. Dewhirst, Associate Solicitor, on the brief) for appellee.

Judge:
Before Markey, Chief Judge, Bennett and Newman, Circuit Judges.

Opinion Text

Opinion By:
Newman, Circuit Judge.

This appeal concerns the administrative rule of the United States Patent and Trademark Office (PTO) whereby an inventor in the field of microbiology is required to deposit a sample of relevant biological materials with an independent depository on or before the date the inventor files a patent application. Such deposit requirement applies only to biological materials that are not readily reproducible from their written description.

The PTO Board of Appeals affirmed the examiner's rejection of claims 1 and 2 of patent application Serial No. 247,656 entitled "High Fusion Frequency Fusible Lymphoblastoid Cell Line", invention of Robert L. Lundak, for failure to meet the requirements of 35 U.S.C. §112, first paragraph, due to Lundak's failure to make such deposit on or before his filing date. A deposit seven days after the filing date was held not to cure the deficiency. The PTO also refused to change Lundak's filing date to the date of the deposit.

Background

The appealed claims are directed to a new human cell line and the hybridomas resulting from its fusion with lymphoid cells. These hybridomas are useful to secrete immunoglobulins derived from the cell line, in turn useful for diagnostic and therapeutic purposes. Claims 1 and 2 are as follows:

1. An immortal B-cell line WI-L2-729HF $_2$.

2. A hybridoma resulting from the fusion of an immunized lymphocyte and a cell line according to Claim 1.

The new cell line was developed by mutagenesis and selection from a known cell line, by procedures that fill twelve pages of Lundak's specification, and include experimental details such as the following:

EXPERIMENTAL

> A HAT-medium sensitive mutant cell line was obtained by subjecting the known human lymphoblastoid B-cell line WI-L2 to increasing concentrations of 6-thioguanine and isolating mutants resistant to 6-thioguanine. A thioguanine-resistant clone was isolated and designated UC 729-6. The UC 729-6 cells are routinely grown in RPMI 1640 media supplemented with 10% FCS, 2m *M* glutamine and 10 -4M 6-thioguanine. UC 729-6 doubles in concentration every 17 hours.
>
> The above cells were then grown at very high densities, approximately 1-1.5X11 7[sic] cell/ml and at this high confluent density, the cells were shifted slowly into ever-decreasing concentrations of fetal calf serum. The concentration of fetal calf serum was decreased by 2% each week from the original 15% and the cells were seeded at high densities i.e. 5X10 6cells per transfer. Following four months of successive transfers, the cells grew on 2% FCS in Iscove's synthetic medium (Iscove and Melchers, *supra),* but not in Iscove's synthetic medium by itself.
>
> Iscove's media was conditioned with growing mouse peritoneal fibroblasts in the presence of about 10mg insulin. Monolayers of mouse fibroblasts in their second or third doubling (in some cases as much as five doublings, but not greater), were incubated with Iscove's synthetic media for 24 hours. This conditioned media was then used 50-50 with normal Iscove's media to shift the

> modified 729 cells into serum-free conditions. Out of about 50 flasks of cells, one flask developed qualities that would grow in Iscove's serum-free media and that cell line was continued. These cells showed no improvement in fusion frequency.
>
> These cells were cloned out to limiting dilutions so that each population was an expansion of a single cell. Each of these populations (approximately 900) were grown into colonies of approximately 5x10 7cells and these cells were fused with human lymphocytes in a procedure using polyethylene glycol 1000 elevated to pH8.2 and containing 15% dimethylsulfoxide and incubated at 27°C for 8.5 minutes. [and so on]

Because of the uncertainties of reproducibility that inhere in such processes, at least in the present state of biotechnology, this invention is of the class covered by the deposit requirement. Robert Lundak, a professor at the University of California, filed an application for patent on March 26, 1981, apparently in the belief that samples of his new cell line had been deposited with the American Type Culture Collection (ATCC), a recognized depository for biological materials. However, this deposit was not made until April 2, 1981.

The examiner cited no prior art, but rejected Lundak's claims under 35 U.S.C. § 112, first paragraph, as nonenabling for failure to meet the criteria of Manual of Patent Examining Procedure (MPEP) § 608.01(p)C, as follows:

C. DEPOSIT OF MICROORGANISMS

> Some inventions which are the subject of patent applications depend on the use of microorganisms which must be described in the specification in accordance with 35 U.S.C. 112. No problem exists when the microorganisms used are known and readily available to the public. When the invention depends on the use of a microorganism which is not so known and readily available, applicants must take additional steps to comply with the requirements of § 112.
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> *In re Argoudelis, et al.,* 168 USPQ 99 (CCPA, 1970), accepted a procedure for meeting the requirements of 35 U.S.C. 112. Accordingly, the Patent and Trademark Office will accept the following as complying with the requirements of § 112 for an adequate disclosure of the microorganism required to carry out the invention:
>
> (1) the applicant, no later than the effective U.S. filing date of the application, has made a deposit of a culture of the microorganism in a depository affording permanence of the deposit and ready accessibility [sic] thereto by the public if a patent is granted, under conditions which assure (a) that access to the culture will be available during pendency of the patent application to one determined by the Commissioner to be entitled thereto under 37 CFR 1.14 and 35 U.S.C. 122, and (b) that all restrictions on the availability to the public of the culture so deposited will be irrevocably removed upon the granting of the patent;
>
> (2) such deposit is referred to in the body of the specification as filed and is identified by deposit number, name and address of the depository, and the taxonomic description to the extent available is included in the specification; and
>
> (3) the applicant or his assigns has provided assurance of permanent availability of the culture to the public through a depository meeting the requirements of (1). Such assurance may be in the form of an averment under oath or by declaration by the applicant to this effect.
>
> A copy of the applicant's contract with the depository may be required by the examiner to be made of record as evidence of making the culture available under the conditions stated above.

In exchanges between Lundak and the ATCC, and Lundak and the examiner, Lundak eventually established to the examiner's satisfaction that the deposit would be maintained for at least thirty years, for which the entire fee was required (by ATCC as well as by the PTO) to be paid in advance, and that the deposit would be replaced by Lundak as necessary to assure its viability. The criteria of MPEP § 608.01(p)C were then deemed satisfied except for the unalterable fact that the deposit had been made seven days after the patent application was filed.

Lundak sought relief first by petition to the Commissioner, to change his filing date from March 26, 1981 to April 2, 1981. The Commissioner denied the petition, stating that there was no indication that the application was not complete as of March 26, 1981 "for the purposes of having a filing date accorded thereto."

Lundak duly appealed the examiner's rejection under section 112 to the Board of Appeals, arguing *inter alia* that he had deposited the cell line with colleagues at the University of California and elsewhere. Sitting in an expanded panel, the Board affirmed the rejection. In its opinion, joined by twelve of the eighteen members of the panel, the Board held that Lundak's deposit of the cell line at university laboratories was inadequate to meet the legal require

ments because they were not "recognized depositories" which could guarantee permanent availability. The Board also stated that such deposit would not meet the terms of the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure, April 28, 1977, 32 U.S.T. 1241, T.I.A.S. No. 9768, to which the United States is a signatory, because *inter alia* the academic institutions had not agreed to maintain the cultures for the required period.

The Board also held that Lundak's deposit made with the ATCC after his filing date could not overcome the section 112 rejection because this deposit was "new matter", proscribed by 35 U.S.C. § 132.

The Board's opinion was accompanied by two concurring opinions. Four Board members affirmed the rejection on the ground that Lundak had failed to overcome a prima facie case of non-enablement. In their view a failure to deposit the biological material with an independent depository on or before the filing date should not be fatal, since this is not the sole means by which evidence of enablement can be presented. They would have allowed Lundak to present additional evidence of the existence of this cell line at the time of his filing date, to overcome the rejection under section 112.

Two other concurring Board members observed that based on *Feldman v. Aunstrup,* 517 F.2d 1351, 186 USPQ 108 (CCPA 1975), *cert. denied,* 424 U.S. 912, 188 USPQ 720 (1976), an applicant must meet two conditions in order to comply with section 112. First, the PTO must be assured of access to the microorganism during pendency, as required by 35 U.S.C. § 114; and second, the public must be assured of access to the material after issuance of the patent. These Board members observed that the first condition was met by Lundak's statement concerning his possession and retention of the cell line at the university. The second condition, that the cell line be permanently available to the public after patent grant, in their view had not been met because Lundak had not proven that the material deposited with the ATCC was the same as the material "in his possession on March 26, 1981".

On reconsideration, the Board noted that Lundak had clarified the terms of his deposit with ATCC; the Board was now satisfied that the deposit conformed with the requirements of MPEP § 608.01(p)C relating to the term and conditions under which it would be maintained. The Board adhered to its decision on all other grounds. [2]

Lundak sought alternative relief in this court: from the Commissioner's decision refusing to change the filing date, by an action in the nature of mandamus pursuant to 28 U.S.C. §1651; and by appeal from the Board's decision holding the original filing to be non-enabling under 35 U.S.C. § 112. On determining that these actions arose from the same set of facts, the substance of the mandamus action was consolidated into the appeal by our order of March 20, 1985.

Analysis

A.

Section 112, first paragraph, requires that the written description in the specification enable any person with skill in the pertinent art to make and use the claimed invention. Compliance with section 112 is negated if undue experimentation is needed because of an inadequate or incomplete description. *W.L. Gore & Assocs., Inc. v. Garlock, Inc.,* 721 F.2d 1540, 1557, 220 USPQ 303, 316 (Fed. Cir. 1983), *cert. denied,* 105 S.Ct. 172 (1984); *In re Strahilevitz,* 668 F.2d 1229, 1232, 212 USPQ 561, 563-64 (CCPA 1982).

When an invention relates to a new biological material, the material may not be reproducible even when detailed procedures and a complete taxonomic description are included in the specification. Thus the then Patent Office established the requirement that physical samples of such materials be made avail

able to the public, as a condition of the patent grant. *See* Levy & Wendt, "Microbiology and a Standard Format for Infra-Red Absorption Spectra in Antibiotic Patent Applications," 37 J. Pat. Off. Soc'y 855 (1955).

The Court of Customs and Patent Appeals considered this requirement in *In re Argoudelis,* 434 F.2d 1390, 168 USPQ 99 (CCPA 1970). Argoudelis had deposited his biological material with a Department of Agriculture depository prior to filing his patent application, but had restricted access to the deposit during the pendency of the patent application to persons authorized by the patent applicant. Upon issuance of the patent, access was to be unrestricted. On the question of whether Argoudelis' deposit made his disclosure enabling despite the restriction on public access prior to grant of the patent, the court endorsed the procedures followed by Argoudelis. *See* MPEP § 608.01(p)C, *supra.*

In 1975 the court elaborated on the role of deposits in connection with the requirements of section 112 in *Feldman v. Aunstrup, supra.* Aunstrup, the senior party in an interference, had deposited samples of his microbiological material at a private, recognized depository in the Netherlands prior to his filing date, specifying that the deposit was to be made available only to Aunstrup's designees. Aunstrup removed all restrictions on the deposit twenty-eight months after filing his U.S. patent application. Feldman, the junior party, contended that the terms of Aunstrup's deposit in the Netherlands failed to assure availability of the sample to the PTO during pendency of the application and to the public upon issuance of the patent, as required by *Argoudelis. Feldman,* 517 F.2d at 1352-53, 186 USPQ at 110-11.

The *Feldman* court, affirming the Board of Patent Interferences, held that under 35 U.S.C. § 114 and 37 C.F.R. § 1.93 "there is no question that the PTO *could* obtain access to [the deposit] *through Aunstrup* at any time during pendency" of the application. *Id.* at 1354, 186 USPQ at 112. As for assuring public access, the court affirmed that although Argoudelis had placed his microorganism in a public depository in the United States, it was not fatal that Aunstrup had followed a somewhat different procedure:

> [T]he enablement requirement of § 112, first paragraph, does not require such assured access to a microorganism deposit *as of the filing date;* what is required is assurance of access to the microorganism culture by the public upon issuance of a patent on the application) prior to *or during the pendency* of the application, so that, upon issuance of a U.S. patent on the application, "the public will, in fact, receive something in return for the patent grant." *In re Argoudelis,* 434 F.2d at 1394, 58 CCPA at 776 (Baldwin, J., concurring).

Id. at 1355, 186 USPQ at 112-13. The court held that Aunstrup's deposit in the Netherlands was adequate for these purposes despite the private nature of the depository and its foreign location, and that the controlling criteria were the permanent availability of the culture and assurance of access upon issuance of the patent. *Id.* at 1355, 186 USPQ at 112.

Analyzing 35 U.S.C. § 112, the *Feldman* court held that the factors enumerated in *Argoudelis* were not "mandatory for a sufficient specification", and that "the so-called 'second aspect' or second function of § 112, first paragraph - that of establishing the application filing date as the prima facie date of invention - was satisfied by Aunstrup's specification." 517 F.2d at 1355, 186 USPQ at 112-13. The court stated "the invention recited in the count and described in the application was fully capable of being reduced to practice (i.e., no technological problems, the resolution of which would require more than ordinary skill and reasonable time, remained in order to obtain an operative, useful process)." *Id.* at 1355, 186 USPQ at 113. That is, the court concluded that Aunstrup's specification was sufficient for constructive reduction to practice.

The *Argoudelis* and *Feldman* decisions recognized the salutary purposes of the system of deposit of biological samples from the perspectives of the inventor, the PTO in fulfilling its duty to administer the patent statute, and the public. These decisions support the reasonableness of the PTO's procedures. Accordingly, MPEP § 608.01(p)C does not specify whether the deposit be in a private or public depository, or in the United States or a foreign country. Its requirement that the deposited culture be available to the PTO during the pendency of the patent application is, as established in *Feldman,* satisfied by compliance with a request from the PTO to the applicant.

We see no controlling distinction between the PTO's mode of access to Aunstrup's deposit in the Netherlands or Argoudelis' in the United States, and to Lundak's cell line at the University of California. In each case, the PTO would proceed by request to the inventor. This is the long-standing procedure of 35 U.S.C. § 114:

§ 114. Models, specimens

> The Commissioner may require the applicant to furnish a model of convenient size to exhibit advantageously the several parts of his invention. When the invention relates to a composition of matter, the Commissioner may require the applicant to furnish specimens or ingredients for the purpose of inspection or experiment.

On the basis of this precedent, Lundak's deposit in his laboratory or in the laboratories of colleagues suffices to meet the requirements of 35 U.S.C. § § 112 and 114 as they apply to pending patent applications. The PTO has the statutory right to request "specimens or ingredients" from the applicant. It is not material whether this request is filled directly by the applicant, or on the instructions of the applicant by a third person to whom the applicant has entrusted the specimen.

With respect to assurance of availability of the material to the public after the grant of the patent, the Board held, in its decision on reconsideration, that the terms of Lundak's ATCC deposit now satisfy the preservation and public disclosure requirements and that this is "no longer an issue in this appeal".

[1] We conclude that 35 U.S.C. § 112, first paragraph, does not require the transfer of a sample of the invention to an independent depository prior to the filing date of the patent application. The requirements of PTO access to a sample of Lundak's cell line during pendency, and public access after grant, were met by Lundak's procedures. Lundak's deposit with the ATCC, which was made after filing but prior to issuance of his patent, and which is referred to in his specification, meets the statutory requirements.

B.

The PTO also argues that a pre-filing deposit with an independent depository, referred to in the specification at the time of filing, is essential to ensure that the disclosure is enabling as of the filing date, which in turn is required so that the filing date may be taken as the date of constructive reduction to practice. The PTO asserts that a post-filing deposit is barred as "new matter", as is the insertion into the specification of reference to such deposit.

The PTO relies on *In re Glass,* 492 F.2d 1228, 181 USPQ 31 (CCPA 1974), which ruled that Glass could not supplement his disclosure after filing by referring to publications that became available after his filing date. The court held that "[t]he sufficiency [of the disclosure] must be judged as of the filing date," *id.* at 1232, 181 USPQ at 34, and set forth two rationales supporting this holding. First, that "35 U.S.C. 132 prohibits adding any 'new matter' to the disclosure after filing." Second, that "the filing date becomes a date of constructive reduction to practice in determining priority of invention and this should not be the case unless at that time, without waiting for subsequent disclosures, any person skilled in the art could practice the invention from the disclosure of the application." *Id.*

The Solicitor argues that to achieve constructive reduction to practice the deposit must be made before filing and incorporated by written reference into the specification as filed, and lacking this the specification is fatally and incurably flawed. Lundak's specification did not identify the actual location of a sample at the time of filing, although it did name the ATCC as the intended location of the sample.

As we consider this question we look first to the statute. 35 U.S.C. § 112 states that the specification must contain a "written description" which must "enable" the practice of the invention by others. The examination for patentability proceeds solely on the basis of the written description. From the examination standpoint, completeness of Lundak's written description was conceded. [3] Although a sample is not a written description, Feldman established that the availability of a sample to the public after the patent has issued will meet the enablement requirement. On point is *In re Hawkins,* 486 F.2d 569, 574, 179 USPQ 157, 161 (CCPA 1973), wherein the court observed that:

> In *Argoudelis,* we rejected the board's proposition that section 111 of the statute requires that the specification must be enabling as filed. We again reject it. . . . [T]he function of section 112 in ensuring *complete public disclosure* is only violated if the *disclosure* is not complete *at the time it is made public,* i.e., at the issue date. (citations omitted).

Hawkins dealt with the question of new matter, wherein the enabling information added was the full text of previously referenced British patent applications. *See also White Consolidated Industries, Inc. v. Vega Servo-Control, Inc.,* 713 F.2d 788, 218 USPQ 961 (Fed. Cir. 1983), wherein an essential element of the invention was not disclosed, but was kept as a trade secret during pendency and after issuance of the patent. The court held that the disclosure was not enabling as filed, i.e., not fully capable of being reduced to practice, see *Feldman, supra.* In *White Consolidated* there was no attempt to add the information, as in *Hawkins,* and *White Consolidated* did not consider whether such information would have been new matter under the facts of the case. In

Lundak's case, the PTO argues that both the deposit and its accession number are new matter.

Argoudelis, Feldman, and related precedent make clear that the requirements for constructive reduction to practice were met on filing their patent applications, and we have today held that it is not material whether a sample of Lundak's cell line resided in his hands or in the hands of an independent depository as of his filing date. An accession number and deposit date add nothing to the written description of the invention. They do not enlarge or limit the disclosure. This is not the shape of new matter against which section 132 was designed to guard.

Constructive reduction to practice does not turn on the question of who has possession of a sample, and thus it does not turn on the inclusion or absence, in the specification as filed, of the name and address of who will have possession of the sample on grant of the patent.

[2] We conclude that Lundak's specification as filed met the requirements of constructive reduction to practice, and that the insertion of depository data after filing is not new matter under 35 U.S.C. § 132.

C.

Both parties raised a number of additional points, all of which have been considered. We comment only on the PTO argument that failure to require a deposit with an independent depository before filing may lead to sham patent applications. We take note of how easily such a supposed safeguard could be subverted by the dishonest, while being unnecessary to the honest: the deposit required by MPEP § 608.01(p)C is not made with the PTO or its designee, but with a third person, perhaps in a foreign country; the examiner must rely solely on the inventor's documentation; the sample in no way aids the patent examination, which is based on the written description in the specification. There is no greater or less risk of dishonesty in this procedure than in any other.

Conclusion

The Board's decision upholding the rejection of Lundak's patent application for failure to comply with 35 U.S.C. § 112, first paragraph, is reversed.

REVERSED.

Footnotes

Footnote 1. In support of its decision the Board stated that "[t]he PTO's interpretation of the statute is for the microbiologist's express benefit." We commend the concern reflected in this statement, and observe that it is the public interest in the progress of the useful arts that is benefitted as new technologies evolve. An interpretation of the statute to deny patent rights in microbiological inventions would be contrary to law. *Diamond v Chakrabarty*, 447 U.S. 303, 309, 206 USPQ 193, 197 (1980), established that "respondent's micro-organism plainly qualifies as patentable subject matter." As the Court said, quoting Thomas Jefferson, "ingenuity should receive a liberal encouragement." *Id.* at 308, 206 USPQ at 197. The PTO must continue to adapt its procedures to facilitate the advance of science and technology.

Footnote 2. The Commissioner no longer relies on the Board's concern for compliance with the Budapest Treaty. The Budapest Treaty sets up minimum requirements for maintaining an international depository for microorganisms. As explained by then Commissioner Diamond at 999 O.G. 2 (October 7, 1980), "[e]ach such depository will be authorized to receive and store deposits, and dispense samples thereof, in compliance with the Treaty and the patent laws of each State adhering thereto." That is, individual patent applications are governed by the national patent laws.

Footnote 3. The Commissioner insists that Lundak's specification was adequate for examination purposes when filed, even as he insists that Lundak's specification was fatally flawed for lack of the deposit. If so flawed, then in our view it should not have been accepted for examination or given a filing date, *see* 37 C.F.R. § 1.53, and Lundak's alternative plea for relief should have been granted. However, we need not reach this issue.

- End of Case -

ISSN 1526-8535